

REMARKS

I. Introduction

This Amendment is responsive to the May 16, 2006 Office Action and is accompanied by a Petition for One-Month Extension of Time to respond to the Office Action. Claims 1-28 are pending in this application, with claims 2, 3, 13, 14, and 21-28 standing withdrawn. Applicant reserves the right to file a divisional on the subject matter of these withdrawn claims. In the foregoing, independent claims 1 and 12 stand amended and claims 4 and 15 are cancelled and the limitations from these claims added to independent claims 1 and 12. Claims 6 and 17 are also amended in the foregoing amendments.

The specification stands objected to for incorporating, by reference, certain published PCT applications. Applicant has amended the specification to recite the corresponding United States patent number in each instance in place of the cited PCT application. Applicant notes the instruction in the Office Action regarding the proper use of trademarks and believes the trademarks are used substantially correctly in the specification.

II. 35 USC § 112, First Paragraph, Claim Rejections

Claims 1, 4-12, and 15-20 stand rejected under 35 USC § 112, first paragraph, for alleged non-enablement. The Office Action states that the specification is enabling with regard to a method of treating the particular functional somatic syndromes of fibromyalgia and UARS and OSA/H, but does not reasonably provide enablement for treatment of other functional somatic syndromes such as chronic fatigue syndrome, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, Gulf War syndrome, premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, chronic whiplash, restless leg/periodic limb movement syndrome. Applicant respectfully traverses these rejections.

The test for enablement is whether the specification provides sufficient information to one skilled in the art to make and use the claimed invention without undue or unreasonable experimentation. Applicant believes the specification provides full and complete support for the claimed methods for treating the functional somatic syndromes. The specification fully describes one or more treatment procedures and identifies suitable apparatus for accomplishing, at least in part, the procedures for treating the functional somatic syndromes

or symptoms thereof. As noted in paragraphs [0005] and [0023] of the specification the term “functional somatic syndromes” is an accepted medical term which covers a group of disorders without organic disease explanation, demonstrable structural changes, or established biochemical abnormalities. These paragraphs list the accepted group of disorders that comprise the “functional somatic syndromes”. The methods disclosed in the specification and disclosed apparatus used in the treatment methods may be used to treat any one of the individual functional somatic syndromes enumerated in paragraphs [0005] and [0023], as prominently stated in paragraph [0033] of the specification.

For example, in one embodiment, the treatment apparatus used in the functional somatic syndrome treatment procedure is a mechanical stabilization technique, typically a device in the form of an oral appliance. In another embodiment, the treatment apparatus used in the treatment procedure is a positive airway pressure device and, in one example, a CPAP device. The treatment procedures and exemplary apparatus used in the treatment procedures are disclosed in the specification as being suitable for treatment of any of the enumerated functional somatic syndromes, as noted in paragraph [0033]. Additional support, if needed, is provided in paragraphs [0025-0026] of the specification. The treatment procedures and exemplary treatment apparatus are not limited to the treatment of the two specific functional somatic syndromes identified in the formal Examples in the specification. Accordingly, in summary, the same treatment procedure(s) and exemplary apparatus may be used to treat any one of the functional somatic syndromes, with the two specific “Examples” being provided merely as that, examples. Again, this is specifically taught in paragraph [0033] of the specification, where it is indicated that any airway stabilization technique, e.g. positive airway pressure stabilization or mechanical airway stabilization, may be used as part of the method for treating functional somatic syndromes.

It is respectfully submitted that undue experimentation is not required and in fact, the specification fully teaches how to treat any one of the functional somatic syndromes using an airway stabilization technique which can take the form of mechanical airway stabilization or positive airway pressure stabilization as examples. In light of the complete teaching in the specification as how to practice the claimed methods, reconsideration and withdrawal of the rejections under 35 USC § 112, first paragraph, are respectfully requested.

III. 35 USC § 102(e) Claim Rejections

Claims 1, 6, 7, 11, 12, 17, and 18 stand rejected under 35 USC § 102(e) for anticipation by United States Patent No. 6,769,910 to Pantino. In view of the foregoing amendments adding the limitations of claims 4 and 15 to independent claims 1 and 12, respectively, the anticipation rejections over Pantino are believed to be rendered moot. The rejections pending against the combinations of claims 1 and 4 and 12 and 15 relating to Pantino in view of United States Patent No. 5,954,048 to Thornton and are discussed herein.

IV. 35 USC § 103(a) Claim Rejections

Claims 4, 5, 15, and 16 stand rejected under 35 USC § 103(a) over Pantino in view of Thornton. As the limitations of claims 4 and 15 are now present in independent claims 1 and 12, the subject matter of amended independent claims 1 and 12 is discussed hereinafter. Claims 8, 9, 19, and 20 stand rejected under 35 USC § 103(a) for obviousness over Pantino in view of Thornton, and further in view of United States Patent No. 6,752,766 to Kowallik. Claim 10 stands rejected under 35 USC § 103(a) for obviousness over Pantino in view of United States Patent No. 5,378,686 to Bennett. In view of the following remarks, reconsideration of all of these rejections is respectfully requested.

With respect to the cited references, Pantino discloses an orally-inserted device for treating snoring, bruxism, and temporomandibular joint syndrome ("TMJ"). Thornton discloses a device (10) adapted for a connection to a continuous positive air pressure (CPAP) system (88) and which includes a mouthpiece formed by a pair of upper and lower arches (12, 14). The upper and lower arches (12, 14) may be adjusted to increase the opening of the user's oral passageway. Kowallik discloses a method and device for sleep monitoring. Bennett discloses a therapeutic treatment for fibromyalgia.

Initially, it is noted that withdrawn claims 2, 3, 14, and 15 are directed to an airway stabilization technique that may comprise mechanical stabilization which may be an oral appliance, a tissue distending device, or a stimulation device. As these claims stand withdrawn and are to be pursued in a divisional application, Applicant has amended independent claims 1 and 12 to recite that the airway stabilization technique may be positive airway pressure to focus the pending claims on this elected embodiment present in the non-withdrawn claims and, therefore, expedite prosecution of this application. As noted in the Office Action, Pantino

discloses an apparatus for mandibular repositioning used for the treatment of snoring, bruxism, and TMJ. As discussed in the background section of Pantino (column 2, lines 1-12), TMJ has been associated with a wide variety of physical ailments, including migraine headaches. Most people afflicted with TMJ suffer from a myofacial pain dysfunction syndrome manifested primarily as a muscle problem related to dental/skeletal relationships and tensional factors. The effects of TMJ can range from mild to severe, including pain in the joint area that can extend to the shoulders, back, and neck, and sinus. Pantino further discusses the general use of a mandibular repositioning "oral appliance" apparatus for treatment of TMJ and bruxism and, further, sleep apnea.

Pantino discloses nothing more than a conventional lower jaw repositioning apparatus that is well-known for treating sleep apnea. Such conventional oral appliances are well-known and are, in fact, recited in the specification in paragraph [0030] as possible physical devices which may be used as a treatment apparatus in the claimed methods in independent claims 1 and 12. The recognition in Pantino for treating bruxism and TMJ with such oral appliances does not render obvious the methods of independent claims 1 and 12 wherein an airway stabilization technique is used to treat a patient having a functional somatic syndrome or a symptom thereof. Such oral appliances are known to inherently treat TMJ and bruxism as they are essentially dental appliances that are inserted within the human mouth and will prevent these physical ailments. However, it is incorrect to conclude that, just because such oral appliances inherently treat TMJ and bruxism, that the claimed methods would have been obvious over Pantino. Pantino discloses nothing more than an apparatus that could be used as a mechanical stabilization device in the claimed methods but does not teach or suggest the methods themselves. Nonetheless, in order to clarify the differences over Pantino and avoid any confusion with the teachings therein, the airway stabilization technique has been affirmatively identified in independent claims 1 and 12 as being positive airway pressure and dependent claims 6 and 17 have been amended to eliminate references to TMJ and bruxism. It is clear that Pantino's mechanical oral appliance is not capable of positive airway pressure therapy and is no longer pertinent to independent claims 1 and 12. It is again noted that the changes to claims 1 and 12 are made to focus the claims on the elected embodiment of positive airway pressure

therapy to expedite prosecution of this application, and the non-elected embodiments identified previously remain available for prosecution in a divisional application.

Thornton discloses a device (10) with an insertable oral section comprised by an upper arch (12) and a lower arch (14). A CPAP system may be associated with or connected to the device (10). In a similar manner to Pantino, Thornton discloses nothing more than a conventional CPAP system which is well-known for treating snoring, sleep apnea, and like sleep disorders. The fact that a device such as that disclosed by Thornton could be used as an apparatus to accomplish, in part, the claimed methods in independent claims 1 and 12 does not in and of itself render independent claims 1 and 12 obvious whether considering Thornton alone or in combination with Pantino or vice versa. These references manifest a complete lack of teaching with respect to treating functional somatic syndromes or symptoms thereof with an airway stabilization technique in the form of positive airway pressure therapy as an example. This is particularly true of Thornton. Only Applicant's disclosure provides a teaching with respect to treating a patient with a functional somatic syndrome or symptom thereof with an airway stabilization technique in the form of positive airway pressure as an example. Again, the fact that the Pantino oral appliance and Thornton oral device with CPAP function are capable of possible use in the claimed methods for treating functional somatic syndromes cannot be used as a basis to conclude that the methods set forth in independent claims 1 and 12 would have been obvious over these references. Again, to ensure that there is no confusion over the Thornton oral device with CPAP function, independent claims 1 and 12 affirmatively claim positive airway pressure as a treatment vehicle and the references to TMJ and bruxism in dependent claims 6 and 17 have been deleted which should clarify the present patentable subject matter in the pending claims.

The teachings of Kowallik and Bennett directed to a method and device for sleep monitoring and a therapeutic treatment for fibromyalgia, respectively, do not correct the foregoing deficiencies of Pantino and Thornton. Accordingly, it is respectfully submitted that independent claims 1 and 12 are allowable over the prior art of record and such is respectfully requested.

V. Conclusion

Should the Examiner have any questions regarding any of the foregoing or wish to discuss this application in further detail to advance prosecution, the Examiner is invited to contact Applicant's undersigned representative at the telephone number provided below. Applicants believe an in-person interview could help expedite prosecution of this application and will contact the Examiner upon filing of this amendment to seek such an interview.

Respectfully submitted,

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